510(k) Summary

SEP - 8 2011

Submitter:	Coloplast A/S
Address	Holtedam 1 3050 Humlebaek, Denmark
Company Contact:	Tim Crabtree Regulatory Affairs Manager 612.302.4922
Date Prepared:	August 15, 2011
Device Name:	Exair® Anterior and Posterior Prolapse Repair System
Common Name:	Surgical mesh
Classification Name:	Surgical mesh, polymeric
Classification:	21 CFR §878.3300
Product Code:	OTP
Predicate Devices:	*Exair* Anterior and Posterior Prolapse Repair System (K083499)

Description of Device: The *Exair* Anterior and Posterior Prolapse Repair System is composed of NovaSilk mesh precut into shape with an enlarged or elongated body with four appendages extending out from the main body. The mesh arms for both *Exair* Anterior and Posterior Prolapse Repair Systems are sleeved in 2-mil thick polypropylene to facilitate arm implantation and positioning: sleeves are removed after proper placement of the implant is achieved. The system instrumentation includes a hollow introducer used to create a passage through the tissues and facilitate placement of the mesh arms, and four (4) anterior or two (2) posterior retrievers used to guide the mesh arms in place the tissues for positioning and fixating the mesh body. The system provided sterile and for single use only.

Intended Use: The Coloplast *Exair* Anterior and Posterior Prolapse Repair Systems are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Comparison of Technological Characteristics: The proposed changes in this submission do not affect the materials, design, components or technological features of the *Exair* Anterior and Posterior Prolapse Repair System. .

Substantial Equivalence: The changes cited in this submission do not affect substantial equivalence established in the original submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Coloplast A/S
% Mr. Tim Crabtree
Regulatory Affairs Manager
Coloplast Corp.
1601 West River Road N
MINNEAPOLIS MN 55411

SEP 28 2012

Re: K112386
Trade/Device Name: Exair® Anterior and Posterior Prolapse Repair System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTP
Dated: August 17, 2011
Received: August 18, 2011

Dear Mr. Crabtree:

This letter corrects our substantially equivalent letter of September 8, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

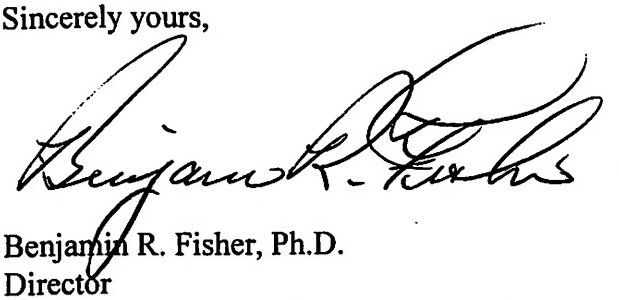
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112386

Device Name: Exair® Anterior and Posterior Prolapse Repair System

Indications for Use: The Coloplast *Exair* Anterior and Posterior Prolapse Repair Systems are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112386